UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PATRICK ARNOLD and ELIZABETH ARNOLD,	)	
Plaintiffs,	)	Civil Action No. 1:08-CV-02168
v.	)	
	)	Chief Judge Holderman
BAXTER HEALTHCARE CORPORATION, a corporation,	)	
Defendant.	)	

DEFENDANT BAXTER HEALTHCARE CORPORATION'S RESPONSE TO MOTION TO REMAND AND REPLY IN SUPPORT OF MOTION TO STAY

This Court need not and should not decide Plaintiffs' motion to remand. The JPML has recently consolidated heparin-related actions into a multidistrict litigation ("MDL") and transferred the MDL proceeding to the Northern District of Ohio. Thus, the most sensible course is to await transfer of this action and allow the MDL court to decide all issues of federal jurisdiction at once.

In the event that the Court reaches the merits of Plaintiffs' remand motion, it should retain jurisdiction. The Supreme Court's decision in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing,* 545 U.S. 308 (2005) ("*Grable*") makes clear that Plaintiffs need not assert a federal cause of action for federal question jurisdiction to apply. Here, substantial and disputed federal questions are apparent from the face of Plaintiffs' complaint – despite Plaintiffs' attempt to downplay the role federal law will play in resolving the issues at stake.

Plaintiffs ask this Court to find Defendant negligent for purportedly failing to comply with FDA approval and inspection requirements for foreign suppliers. Plaintiffs also challenge Defendant's conduct in the very areas in which Defendant was governed by ***and complied with*** specific FDA requirements: manufacture; quality control; warnings; importation and procurement of biomedical products; inspection and approval of foreign suppliers; testing; and recall. Although

framed in the language of state tort law, Plaintiffs' claims directly challenge the FDA's approval and regulation of heparin and the federal regulatory process governing the approval and sale of prescription drugs. Accordingly, federal jurisdiction over Plaintiffs' claims is proper and Plaintiffs' motion to remand should be denied.

ARGUMENT

I. This Court Should Not Address Remand Issues, As The MDL Court Can And Should Decide Issues Related To Federal Jurisdiction In One Proceeding.

The allegations in this case substantially overlap with similar ones made in several other lawsuits filed throughout the United States. These cases have now been consolidated into an MDL proceeding and the MDL has been transferred to Chief Judge Carr in the Northern District of Ohio. (Ex. A) Baxter has notified the panel of this case as a tag-along action for transfer to the MDL, and the MDL panel is expected to issue a conditional transfer order shortly. (Ex. B) Accordingly, transfer of this case is both likely and imminent.

There are at least four other heparin cases that have been removed to federal court based, at least in part, on federal question jurisdiction. All federal jurisdictional issues can and should be handled in a single MDL proceeding to facilitate judicial economy and avoid inconsistent rulings – which are precisely the reasons for establishing the MDL.[1] *See e.g., Johnson v. AMR Corp.*, Nos. 95 C 7659 to 95 C 7664, 1996 WL 164415, at *4 (N.D. Ill. Apr. 3, 1996) (staying proceedings pending ruling by MDL panel on consolidation despite pending motion to remand and noting that MDL court should decide jurisdictional issues).

[1] In their second response to Defendant's motion to stay, Plaintiffs urge the Court to consider their motion to remand before turning to the motion to stay. Supp. Memo. in Resp. to Mot. to Stay, Docket No. 18. But even the authority Plaintiffs cite for this position states that where multiple cases will pose the same questions of remand to an MDL court, "the interests of judicial economy and the threat of inconsistent rulings outweighs the prejudice to the [Plaintiffs] from delay." *Bd. of Trustees of the Teachers' Ret. Sys. of the State of Ill. v. Worldcom, Inc*., 244 F. Supp. 2d 900, 906 (N.D. Ill. 2002).

In one of the other heparin cases that was removed to federal court on the basis of federal question jurisdiction, *Fowler v. Hamilton Medical Center*, No. 4:08-cv-0055-HLM (N.D. Ga.), the court stayed proceedings despite a pending motion to remand. (Ex. C, 5/7/08 Order, at 8 ("Additionally, the transferee court may well be in a better position to address the other motions that remain pending in this case, ***such as the Joint Motion to Remand***. Under those circumstances, granting a stay will conserve judicial resources.") (emphasis added)) Based on its experience with the JPML, the court noted that consolidation and transfer would occur quickly, so any prejudice to parties seeking remand would be minimal. (*Id.* at 7)[2] Here too, the better course would be to allow the MDL court to decide all issues of federal jurisdiction.

II. Federal Jurisdiction Is Proper In This Case, Which Raises A Host Of Federal Questions Related To Nearly Every Aspect Of The FDA's Regulatory Scheme.

Although Plaintiffs' complaint masquerades as an ordinary state-law tort action, it squarely challenges determinations made by the FDA and the adequacy of federal requirements governing the manufacture and sale of prescription drugs. Resolving the allegations in this lawsuit will require a determination that specific aspects of the federal regulatory process governing prescription drugs are insufficient to protect the public health – a determination that clearly involves a substantial question of federal law.

A. Federal Jurisdiction Arises Where The Plaintiff's Claim Requires Resolution Of A Substantial Federal Question.

Plaintiffs seems to contend that they can avoid federal jurisdiction by fashioning their complaint as a "garden variety tort case[ ]" (Mot. at 1) and citing federal law in only "two subparagraphs" of their complaint (*id.* at 5-6). But the exercise of federal jurisdiction is both appropriate and warranted where the real nature of a plaintiff's claim is federal, irrespective of how

[2] The *Fowler* plaintiff later moved for voluntary dismissal and the case has been dismissed. Thus, Defendant's reference to four other cases removed on the basis of federal question jurisdiction does not include *Fowler*.

the plaintiff has tried to characterize his claim. *See, e.g., Jones v. Gen. Tire & Rubber Co.*, 541 F.2d 660 (7th Cir. 1976).

The Supreme Court and other federal courts have readily recognized the existence of federal jurisdiction over claims that, while not created by federal law, nonetheless involve substantial questions of federal law necessary to the plaintiff's right to relief. *See, e.g., City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997); *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 27-28 (1983); *Smith v. Kan. City Title & Trust Co.*, 255 U.S. 180 (1921). While "the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction," it is axiomatic that certain cases depend on the resolution of a federal question sufficiently substantial to arise under federal law. *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 813 (1986) ("*Merrell Dow*"); *see also Ormet Corp. v. Ohio Power Co.*, 98 F.3d 799, 807 (4th Cir. 1996) (same).

In 2005, the Supreme Court reaffirmed the substantial federal question doctrine in *Grable*. After the IRS seized Grable's real property and sold it to satisfy a federal tax delinquency, Grable brought a quiet title action in state court claiming that record title was invalid because the IRS had failed to properly notify Grable of the seizure. The defendant removed the case to federal court as presenting a federal question, because the state claim of title depended on the interpretation of the notice statute in the federal tax law. The Supreme Court granted certiorari to resolve a split within the Courts of Appeals on whether *Merrell Dow* always requires a federal cause of action as a condition for exercising federal-question jurisdiction.

The Court held that a federal cause of action was not required – "th[e] Court having recognized for nearly 100 years that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues." 545 U.S. at 312. The Court explained:

> The [substantial federal question] doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that

> nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues . . . .

Id. The Court determined that the meaning of the federal tax provision is an important issue of federal law that sensibly belongs in a federal court since the Government has a strong interest in the "prompt and certain collection of delinquent taxes and the ability of the IRS to satisfy its claims from the property of delinquents requires clear terms of notice." *Id.* at 315 (citation omitted). "The Government thus has a direct interest in the availability of a federal forum to vindicate its own administrative action," and the other parties "may find it valuable to come before judges used to federal tax matters." *Id.*

Pursuant to *Grable*, federal question jurisdiction is proper where a state-law claim necessarily raises a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities. *Id.* at 321.

B. A Complex Federal Regulatory Scheme For Prescription Drugs Is Set Forth In The Food, Drug, And Cosmetic Act And Accompanying Regulations.

The Federal Food, Drug, and Cosmetic Act ("FDCA") was enacted by the United States Congress pursuant to the power conferred upon it under the Constitution to regulate interstate commerce. 21 U.S.C. §§ 301 *et seq*. The Act's overriding purpose as well as its primary objective is the protection of the public health; the Act is designed primarily to protect consumers from dangerous products. *U.S. v. Bacto-Unidisk*, 394 U.S. 784 (1969); *U.S. v. Undetermined No. of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994); *Gen. Med. Co. v. U.S. Food & Drug Admin.*, 770 F.2d 214 (D.C. Cir. 1985). The Act is designed to protect public health by regulating certain products moving in interstate commerce. *U.S. v. Vital Health Prods., Ltd*., 786 F. Supp. 761 (E.D. Wis. 1992), *aff'd*, 985 F.2d 563 (7th Cir. 1993). In this regard, the Act's main purpose is to prohibit the movement in interstate commerce of adulterated and misbranded drugs, devices, and cosmetics.

State v. Deputy, 644 A.2d 411 (Del. Super. Ct. 1994). Furthermore, one of the Act's primary purposes is to ensure the safety of food and drugs before they become available to the public. *Vital Health Prods., Ltd.*, 786 F. Supp. 761.

The FDA approved Baxter's heparin products only after applying the comprehensive standards set forth in the FDCA and its accompanying regulations. The FDA approval process for new drugs is comprehensive. Applicants must submit, among other things, "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." 21 U.S.C. § 355(b)(1). The formal approval process begins with the manufacturer's submission of an Investigational New Drug application ("IND") to conduct clinical trials. 21 C.F.R. § 312.20. Before filing the IND, the applicant must have subjected biologically active agents of the proposed drug to comprehensive animal and human tissue testing. 21 C.F.R. § 312.23(a). The applicant may commence human clinical trials if the FDA does not request more information or seek modifications to the testing protocols. 21 C.F.R. §§ 312.21-23, 312.40(b)(I). During the next stage of the approval process there are three phases of clinical trials. 21 C.F.R. § 312.21(a)(1), (b), & (c). By statute, the studies conducted must be "adequate and well-controlled." 21 U.S.C. § 355(d); *see* 21 C.F.R. § 314.126(b)(1)-(7). In reviewing the studies, the FDA conducts "an assessment of the scientific quality of the clinical investigations." 21 C.F.R. § 312.22(a). Moreover, the FDA may require additional testing or studies at any stage in the approval process. 21 C.F.R. § 312.4l(a). Throughout, the FDA "monitor[s] the progress of the conduct and evaluation of clinical trials" and is "involved in facilitating their appropriate progress." 21 C.F.R. § 312.87.

After the successful completion of this testing regime, the applicant must submit a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a)-(d); 21 C.F.R. § 314.50. The NDA catalogues

the history of the drug's development and testing. In seeking approval, the applicant must provide "substantial evidence" that the drug is safe and effective. 21 C.F.R. § 314.125(b)(5). This means:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed . . . .

21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.125(b).

In reviewing the scientific evidence regarding a proposed drug, the FDA is required to "establish panels of experts" consisting of "members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacturer, or utilization of such drugs." 21 U.S.C. § 355(n)(1) & (n)(3)(A). In determining whether a drug should be approved, the "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.l05(c).

Significantly, the FDA is barred from approving a drug if it finds the manufacturing process deficient. The FDA "shall issue an order refusing to approve the application" if, among other things, "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d). Furthermore, FDA regulations set forth good manufacturing practices with which drug manufacturers must comply. *See, e.g.*, 21 C.F.R. § 211.1 ("regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals").

The FDCA specifically defines when a drug is adulterated. Pursuant to 21 U.S.C. § 351, a drug is "adulterated," *inter alia*:

> (a)(2)(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or. . . .
>
> (b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made.

The FDCA prohibits the introduction or sale of adulterated drugs into interstate commerce. 21 U.S.C. § 331. Among other things, the FDA has the authority to seize adulterated drugs that are introduced into interstate commerce. 21 U.S.C. § 334.

Even after approving a prescription drug, the FDA continues to evaluate its safety and efficacy. By law, manufacturers must report to the FDA "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a). Prompt report of serious and unexpected adverse drug experiences is required, as is any increase in frequency of a particular adverse event. 21 C.F.R. § 314.80(c)(1). Moreover, the FDA, after due notice and opportunity for hearing to the applicant, is statutorily required to withdraw approval under specified circumstances. 21 U.S.C. § 355(e); *see also* 21 C.F.R. § 314.150.

The FDCA sets forth requirements for drug imports (including for components of drugs). *See, e.g.*, 21 U.S.C. § 381(a) ("The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of . . . drugs . . . which are being imported or

offered for import into the United States . . . . If it appears from the examination of such samples or otherwise that . . . such article is adulterated . . . then such article shall be refused admission . . . .”). The FDA may issue regulations, conduct examinations and investigations, request records of interstate shipments, conduct factory inspections, and so forth. 21 U.S.C. § 371 *et seq*.

The FDCA also closely regulates what information may and may not be disseminated by manufacturers. *See, e.g.*, 21 U.S.C. § 360aaa. Provision is made for the dissemination of information regarding drugs “in situations involving, in the opinion of the Secretary, imminent danger to [the] health or gross deception of the consumer.” 21 U.S.C. § 375(b).[3]

C. Plaintiffs’ Claims Necessarily Raise Substantial And Disputed Questions Of Federal Law By Asking The Court To Interpret These Federal Requirements And Challenging The Federal Regulatory Scheme For Prescription Drugs.

Plaintiffs assert three claims against Defendant: strict liability, negligence, and loss of consortium. Plaintiffs’ strict liability claim charges that Defendant supplied heparin that “was tainted, contaminated, and/or in an irregular condition” and that Defendant failed to warn of the heparin’s “unreasonably dangerous” condition. (Compl. Count I, ¶ 7) Plaintiffs’ negligence claim alleges that Defendant negligently (a) manufactured, distributed, and sold heparin; (b) failed to warn that the heparin was “tainted, contaminated, and/or in an irregular condition”; (c) failed to warn that the heparin was not safe; (d) failed to comply with “all statutes, laws, regulations, and safety codes pertaining to the manufacture, production, distribution, storage, and sale of heparin”; (e) failed to adequately test the heparin; (f) failed to use ingredients, supplies, and other constituent materials, in the production of heparin, that were reasonably safe and “free of contaminants”; (g) failed to take

---

[3] Federal courts are currently split on the scope of preemption by the FDCA, *see, e.g., Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) (finding preemption of failure to warn claim); *In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (same); with the Supreme Court set to clarify the issue in its next term in *Wyeth v. Levine*, an appeal from the Supreme Court of Vermont. The FDA has set forth its view that the FDCA preempts at least labeling/warning claims. 71 Fed. Reg. 3922-01, 3933-35 (Jan. 24, 2006).

reasonable and necessary precautions to prevent contamination of the heparin; (h) failed to exercise reasonable care "in acquiring heparin and/or the ingredients for heparin from producers and suppliers that took reasonable and necessary precautions to prevent contamination; and (i) failed to exercise reasonable care "in acquiring the ingredients for heparin only from producers and suppliers that had undergone proper inspection and evaluation, including, but not limited to, inspection and evaluation by the FDA." (Compl. Count II, ¶ 7) Plaintiffs' loss of consortium claim is based on their allegations of strict liability and negligence. (Compl. Counts III & IV)

Plaintiffs specifically assert in their complaint that Defendant was negligent in procuring biomedical products from foreign suppliers when the facilities and operations of those suppliers had not undergone proper inspection and/or approval by the United States Food and Drug Administration. (Compl. Count II, ¶ 7(i)) Plaintiffs' assertion will require the Court to apply federal law to decide what the federal statute and regulations require and whether inspection and approval requirements were met. Moreover, Plaintiffs place federal law squarely at issue by alleging that Defendant was negligent in failing to comply with applicable statutes, laws, and regulations pertaining to the manufacture, production, distribution, storage and sale of heparin. (Compl. Count II, ¶ 7(d)) Plaintiffs do not dispute that these requirements are federal. (*See* Mot. at 5-6) [4]

In addition, ***all*** of Plaintiffs' claims are predicated on an allegation that the heparin was "tainted, contaminated, and/or in an irregular condition." (*See* Compl. Count I, ¶ 7(a) & (b) & Count II, ¶ 7(a)-(i)) That requires the Court to decide a substantial, disputed issue of federal law. *See, e.g.*, 21 U.S.C. § 351 (defining when a drug is "adulterated").

---

[4] Citing *Samuel Trading, LLC v. Diversified Group, Inc.*, 420 F. Supp. 2d 885 (N.D. Ill. 2006), Plaintiffs maintain that these allegations do not raise a substantial federal issue because it is one of various alternative grounds for relief. (Mot. at 7-8) As discussed further below, however, all of Plaintiffs' claims require resolution of federal law. Moreover, in this case, the need to interpret federal law is central to each count in the complaint. By contrast, in *Samuel Trading*, several counts of the complaint involved no need to interpret federal law.

Plaintiffs' claims also directly challenge the adequacy of numerous, specific aspects of the federal regulatory scheme with which Defendant complied, including, *inter alia*, (1) good manufacturing requirements; (2) warning and labeling requirements; (3) requirements for import of pharmaceutical products; (4) definitions and rules related to "adulterated" drugs; (5) testing requirements; (6) new drug approvals; and (7) adverse event report monitoring. The adequacy of Defendant's compliance with these federal requirements (and, in turn, the adequacy of the requirements themselves) are actually disputed, since Plaintiffs' claims are premised upon the position that they can prevail on state law tort claims despite Defendant's compliance with these aspects of the federal regulatory scheme.[5] Moreover, these issues are substantial; indeed, they are at the heart of Plaintiffs' complaint.

What is more, Plaintiffs' claims expressly challenge the FDA's determinations related to heparin, including its approval of heparin and failure to withdraw approval, as well as its decisions on inspection and approval of the facility that supplied heparin components. In short, Plaintiffs' claims are inextricably intertwined with the comprehensive federal scheme governing prescription drug approval. Because Plaintiffs' claims cannot be decided without the judge or jury second-guessing FDA decisions and assessing the adequacy of the statute and regulations under which the FDA acted, those claims raise a substantial federal question.

A federal district court faced a strikingly similar issue, and held that a substantial federal question existed, in *In re Wireless Telephone Radio Frequency Emissions Products Liability Litigation,* 216 F. Supp. 2d 474 (D. Md. 2002). There, plaintiffs alleged that, because wireless telephones emit radio frequency radiation ("RF"), they are unsafe in the absence of headsets.

---

[5] Plaintiffs claim that the meaning of the FDCA does not appear to be in dispute. (Mot. at 5) To the contrary, Plaintiffs' position that Defendant failed to comply with federal requirements (*see* Compl. Count I, ¶¶ 7(d) & (i)), and Defendant's contention that it complied with such requirements will undoubtedly raise differences regarding what those requirements actually mean. Moreover, both the adequacy of the requirements and Defendant's compliance with them are actually disputed.

Wireless telephones are regulated by the FCC which, in conjunction with the FDA, determined that headsets were not required to protect consumer safety. Even though plaintiffs' complaints sought relief only under various state-law theories, the court held that a review of those complaints "and the remedy plaintiffs request reveals that the true gravamen of these complaints is to attack the lack of a headset requirement under the federal RF safety rules." *Id.* at 488.

The court reasoned that any court deciding whether to force defendants to provide headsets would necessarily have to evaluate whether the FCC's determination adequately protected the public health:

> ***Any court faced with such a class and requested remedy necessarily must evaluate whether the FCC has been authorized by Congress to act as the final authority on the regulation of RF emissions from wireless phones, and whether the current RF requirements promulgated by the FCC adequately protect the public's health.*** Indeed, the FCC has already considered and rejected a headset requirement. Thus, a state imposed headset rule necessarily invalidates the national standard. ***A suit to invalidate a federal regulation as unreasonable arises under federal law.***

Id. at 488-89 (emphasis added; footnote omitted). The court noted that "[w]here the resolution of a federal issue in a state-law cause of action could, because of different approaches and inconsistency, undermine the stability and efficiency of a federal statutory regime, the need for uniformity becomes a substantial federal interest, justifying the exercise of jurisdiction by federal courts." *Id*. at 490 (quoting *Ormet Corp. v. Ohio Power Co.*, 98 F.3d 799, 807 (4th Cir. 1996)).

That reasoning applies with equal force here. Plaintiffs seek a ruling that contradicts the FDA's determinations with respect to approval and sale of heparin. Furthermore, the central premise of Plaintiffs' complaint is that the FDCA and accompanying regulations permitted the sale of a prescription drug that was adulterated and thus unreasonably dangerous to consumers. The only way to grant Plaintiffs the relief they seek is to assess whether the FDCA and accompanying regulations adequately protect the public's health – *i.e.*, "to pass judgment on the validity" of these

standards. *In re Wireless*, 216 F. Supp. 2d at 491. Where, as here, the relief sought would conflict with a federal standard, a plaintiff's claim arises under federal law.

The cases cited by Plaintiffs do not warrant a different result. *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677 (2006), which involved whether federal jurisdiction existed over a reimbursement claim arising from settlement of a state lawsuit, bears no factual similarity to the case at hand. In light of the nature of the federal interest at stake and the degree to which it is implicated, this case is far more akin to the circumstances in *Grable*.[6]

Merrell Dow addressed whether the need to apply a misbranding provision of the FDCA to resolve one count was sufficient to invoke substantial question jurisdiction over the entire six-count complaint. The Court did not address whether federal jurisdiction would exist over a case challenging the adequacy of any FDCA provision, much less myriad specific aspects of the FDCA's regulatory scheme. Nor did the Court issue a blanket ruling that no case involving the FDCA could arise under federal law as Plaintiffs suggest. (*See* Mot. at 5) Moreover, concerning *Merrell Dow*, the *Grable* court noted:

> *Merrell Dow* cannot be read whole as overturning decades of precedent, as it would have done by . . . converting a federal cause of action from a sufficient condition for federal-question jurisdiction INTO A NECESSARY ONE . . . . In the first place, *Merrell Dow* disclaimed the adoption of any bright-line rule, as when the Court reiterated that "in exploring the outer reaches of § 1331, determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system." 478 U.S. at 810. . . .

---

[6] Post-*Grable* (and *Empire*), courts have found substantial federal question jurisdiction over state law claims in a variety of circumstances. *E.g., Nicodemus v. Union Pac. Corp*., 440 F.3d 1227 (10th Cir. 2006) (landowners' claims for trespass, unjust enrichment, and slander of title hinged on whether use of rights-of-way granted pursuant to federal land-grant statutes exceeded purpose for which they were granted and thus raised disputed issues of federal law); *In re Nat'l Sec. Agency Telecomm. Records Litig.*, 483 F. Supp. 2d 934 (N.D. Cal. 2007) (state-law privacy claims against telephone companies for alleged release of calling records to National Security Agency gave rise to federal question jurisdiction where application of state secrets doctrine presented disputed and substantial question); *Adventure Outdoors, Inc. v. Bloomberg*, 519 F. Supp. 2d 1258 (N.D. Ga. 2007) (removal proper where court had to determine whether gun brokers' sales to investigators violated federal law to decide brokers' negligence and defamation claims); *In re Pharm. Indus. Average Wholesale Price Litig*., 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (interpretation of "average wholesale price" provision of federal Medicare statute raises substantial federal question).

545 U.S. at 317.

Bennett v. Southwest Airlines Co., 484 F.3d 907 (7th Cir. 2007), rejected the sweeping proposition that all product liability suits involving commercial air travel belong in federal court because federal aviation standards sometimes play a role. *Id.* at 909. Critically, plaintiffs in *Bennett* did not challenge the validity of any specific action by a federal agency, and the Seventh Circuit specifically noted that if the validity of the agency's actions were at stake, it would have reached a different result. *Id.* The removing defendants in *Bennett* did not point to any particular disputed issue of federal law. In addition, unlike in this case, the need for uniformity was not of great concern. *Id.* at 911 ("How flights proceed while airborne, and which safety devices an airframe should carry, may well be subjects on which only one national rule is tolerable. Many other subjects, however, vary from airport to airport.")

D. The Federal Courts Can And Should Exercise Jurisdiction Here Without Disturbing Any Congressionally Approved Balance Of Judicial Responsibilities.

Key factors for determining whether federal jurisdiction will be imposed include the importance of the federal interest and whether the exercise of jurisdiction will result in a flood of federal cases. *See Grable*, 545 U.S. at 321; *Ormet Corp.*, 98 F.3d at 806-07 (determination "should be informed by a sensitive judgment about whether the existence of federal judicial power is both appropriate and pragmatic"; "where the resolution of a federal issue in a state-law cause of action could, because of different approaches and inconsistency, undermine the stability and efficiency of a federal statutory regime, the need for uniformity becomes a substantial federal interest").

Here, the need for uniformity is compelling, because Plaintiffs' lawsuit raises the potential for disparate requirements for the approval, manufacture and sale of prescription drugs, imposed by courts throughout the country, that could both conflict with and undermine the regulatory framework designed to provide a uniform standard for assuring the safety and efficacy of prescription drugs. Indeed, the federal interests at stake, including the need for uniformity, are

particularly compelling here given the centrality of the allegations in the complaint that prescription drug components were adulterated and imported from a foreign facility that was not properly FDA-inspected and approved. (*See* Compl. Count II, ¶¶ 7(h) & (i))[7] The need for standard and uniform federal requirements relating to importation from and inspection of foreign facilities is a critical federal interest. *See S-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 96 (1984) (a higher level of scrutiny is required for state actions restraining foreign commerce because, unlike interstate commerce, the United States must speak with a single voice for effective relations and trade with foreign nations); *Japan Line, Ltd. v. County of Los Angeles*, 441 U.S. 434, 448 (1979) ("[f]oreign commerce is pre-eminently a matter of national concern"). At bottom, the centrality and sensitivity of these federal issues distinguish this case from product liability actions that only peripherally raise federal issues, including federal standards.

Moreover, the floodgates will not open from the exercise of jurisdiction under the circumstances. Defendant does not seek a ruling that all state law product liability claims that implicate federal standards – no matter how indirectly – are subject to federal jurisdiction. Defendant simply seeks a ruling that, pursuant to the sensitive, case-by-case inquiry required by the Supreme Court's decisions, federal jurisdiction is appropriate here given the significant scope and nature of Plaintiffs' challenges to federal requirements and determinations.

[7] It has been well publicized and the subject of a public Congressional hearing that the crude heparin was sourced from China and that Baxter's supplier operated a manufacturing facility in China.

CONCLUSION

Defendant respectfully requests that this Court grant its motion for stay and refrain from ruling on Plaintiffs' remand motion or, in the alternative, that the Court deny Plaintiffs' motion.

This the 17th Day of June, 2008.

Respectfully submitted,

/s/ Leslie M. Smith, P.C.
Leslie M. Smith, P.C., Attorney No. 6196244
Kirkland & Ellis LLP
200 East Randolph Drive
Chicago, IL 60601
telephone: (312) 861-2000
facsimile: (312) 861-2200

Attorney for Baxter Healthcare Corp.

EXHIBIT A

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION MDL No. 1953

TRANSFER ORDER

Before the entire Panel: Plaintiff in the Southern District of Florida action moves, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings of this litigation. No responding party opposes centralization, but there is disagreement over the selection of a transferee forum. Movant and responding plaintiffs suggest centralization in the districts in which their actions are pending – the Southern District of Florida, the Northern District of Ohio or the District of Puerto Rico; at the Panel hearing session, movant also proffered the Northern District of California. Defendants[1] prefer selection of either the Northern District of Illinois or the District of New Jersey; also, defendants stated during oral argument before us that they do not object to centralization in the Northern District of Ohio. Plaintiffs in various potential tag-along actions either support one of these districts or suggest the Western District of Pennsylvania or the Western District of Wisconsin. The latter is the alternative choice of plaintiff in the District of Puerto Rico action included in the motion. Plaintiffs in one potential tag-along action pending in the District of New Jersey do not advocate centralization in a specific district, but urge the Panel to select a transferee district which can undertake active management of these proceedings on a priority basis.

This litigation presently consists of three actions listed on Schedule A and pending in three districts as follows: one action each in the Southern District of Florida, the Northern District of Ohio, and the District of Puerto Rico.[2]

On the basis of the papers filed and hearing session held, we find that the actions in this litigation

---

[1] Baxter Healthcare Corp., Baxter International, Inc., and Baxter Healthcare Corp. of Puerto Rico (collectively Baxter); and Scientific Protein Laboratories, LLC.

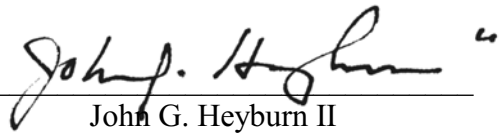
[2] The Panel has been notified that twenty other related actions have recently been filed, six actions in the Northern District of Ohio, four actions in the Northern District of Illinois, two actions each in the District of New Jersey and the District of Puerto Rico, and one action each in the Middle District of Florida, the Northern District of Georgia, the Eastern District of Louisiana, the Eastern District of Tennessee, the Eastern District of Texas and the Western District of Pennsylvania. These actions will be treated as potential tag-along actions. *See* Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

involve common questions of fact, and that centralization under Section 1407 in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions share factual questions relating to the manufacture and sale by Baxter of allegedly adulterated Heparin causing economic or personal injuries; this Heparin was recalled in February 2008. Centralization under Section 1407 will eliminate duplicative discovery; avoid inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary.

We are persuaded that the Northern District of Ohio is an appropriate transferee district for this litigation. Seven of the 23 known actions are pending in this district mostly before Judge James G. Carr who has the time to devote to this docket.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the Northern District of Ohio are transferred to the Northern District of Ohio and, with the consent of that court, assigned to the Honorable James G. Carr for coordinated or consolidated pretrial proceedings with the action pending there and listed on Schedule A.

PANEL ON MULTIDISTRICT LITIGATION



John G. Heyburn II
Chairman

D. Lowell Jensen
Robert L. Miller, Jr.
David R. Hansen
J. Frederick Motz
Kathryn H. Vratil
Anthony J. Scirica

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION MDL No. 1953

SCHEDULE A

Southern District of Florida

David D'Amico v. Baxter Healthcare Corp., et al., C.A. No. 9:08-80311

Northern District of Ohio

Leroy Hubley, etc. v. Baxter Healthcare Corp., et al., C.A. No. 3:08-377

District of Puerto Rico

Esther S. Rivera v. Baxter International, Inc., et al., C.A. No. 3:08-1368

EXHIBIT B

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE HEPARIN PRODUCTS LIABILITY LITIGATION,	)	MDL Docket No. 1953

NOTICE OF TAG-ALONG ACTIONS

Pursuant to Rule 7.5(e) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Defendants BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION OF PUERTO RICO hereby notifiy the Clerk of the Panel of the tag-along actions listed on the attached Schedule A and state as follows:

1. On March 28, 2008, plaintiff in *D'Amico v. Baxter Healthcare Corp.*, No. 9:08-cv-80311-KAM (S.D. Fla.) filed a motion before the Judicial Panel on Multidistrict Litigation for the transfer and consolidation of related pending cases in MDL No. 1953, In re Heparin Products Liability Litigation.

2. Additional related actions are now pending in various district courts across the country. These actions involve questions of fact and law common to the action subject to the previous *D'Amico* motion for transfer and consolidation.

3. Those additional, related actions are listed in Schedule A of this Notice.

DATED: April 22, 2008

Respectfully Submitted,

Andrew P. Bautista

Andrew P. Bautista
KIRKLAND & ELLIS, LLP
200 East Randolph Drive
Chicago, Illinois 60601
telephone: 312-861-2000
facsimile: 312-861-2200

SCHEDULE A - Notice of Tag-Along Actions
***In re Heparin Products Liability Litigation,* MDL No. 1953**

Caption	Civil Action No.	District Court	Judge
Baxter v. Baxter Healthcare Corporation, *et al.*	3:08-cv-00988-JGC	Northern District of Ohio	Judge James G. Carr
LaCourse v. Baxter Healthcare Corporation, *et al.*	3:08-cv-00986-DAK	Northern District of Ohio	Judge David A. Katz
Staples v. Baxter Healthcare Corporation, *et al.*	3:08-cv-00984-JGC	Northern District of Ohio	Judge James G. Carr
Collier v. Baxter Healthcare Corporation, *et al.*	3:08-cv-00987-JGC	Northern District of Ohio	Judge James G. Carr
Arnold v. Baxter Healthcare Corporation	1:08-cv-02168	Northern District of Illinois	Judge James Holderman
Rosado Fontanes, *et al.* v. Baxter International, Inc., *et al.*	3:08-cv-01455-CC	District of Puerto Rico	Judge Carmen C. Cerezo
DiSciullo v. Baxter Healthcare Corporation, *et al.*	2:08-cv-00547-DSC	Western District of Pennsylvania	Judge David S. Cercone

CERTIFICATE OF SERVICE

I, Andrew P. Bautista, hereby certify that on April 22, 2008, I caused to be served a copy of the foregoing NOTICE OF TAG-ALONG ACTIONS, by overnight delivery upon:

Clerk of the Panel
Judicial Panel on Multidistrict Litigation
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E.
Room G-255, North Lobby
Washington, D.C. 20002-8004

And by First Class Mail upon:

See attached Service List.

DATED: April 22, 2008

Andrew P. Bautista

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

Nancy Ann Fowler,
et al.,

Plaintiffs,

v. CIVIL ACTION FILE
NO. 4:08-CV-0055-HLM

Hamilton Medical Center, Inc.,
et al.,

Defendants.

ORDER

This case is before the Court on Defendant Baxter Healthcare Corporation's Motion to Stay Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation ("Motion to Stay") [11].

I. Background

Defendant Baxter Healthcare Corporation ("Defendant Baxter") has moved to stay all of the proceedings in this

case pending a decision by the Judicial Panel on Multidistrict Litigation ("JPML") on various motions to transfer filed in this case and in related cases. Defendant Baxter argues that pretrial discovery in the cases will overlap, that consolidation in one transferee court is appropriate, and that staying the proceedings in this case will further the interests of judicial economy and efficiency by eliminating unnecessary duplication of litigation. Defendant Baxter further contends that if the Court refuses to stay the proceedings in this case, Defendant Baxter will be placed in the position of having to develop and present similar defenses in separate federal district courts.

The other Defendants in this litigation apparently oppose the Motion to Stay, and instead argue that an Order remanding this case to the Superior Court of Whitfield

County, Georgia, is appropriate. As of the date of this Order, Plaintiffs have not responded to Defendant Baxter's Motion, and the time for doing so has expired.[1]

II. Discussion

28 U.S.C.A. § 1407 permits the transfer of cases pending in different districts that involve common questions of fact to the same district for coordinated or consolidated

---

[1]The Court directs counsel to comply with the provisions of the Local Rules governing reply briefs, amended briefs, and surreply briefs. Specifically, counsel ordinarily must obtain permission from the Court prior to filing an amended brief or a surreply brief. The Court will direct the Clerk to strike all future briefs filed by the parties that do not comply with this rule, and will require the parties to re-file those briefs after obtaining permission from the Court to file the briefs.

The Court also refers counsel to the response time requirements set forth in the Local Rules. Ordinarily, parties must respond to Motions, other than summary judgment motions, within ten business days, plus three days for mailing. By the Court's calculation, the Georgia Defendants' response to Defendant Baxter's Motion to Stay, and Plaintiffs' response to that Motion, were due on May 6, 2008, not May 1, 2008, as Defendant Baxter asserts.

pretrial proceedings. 28 U.S.C.A. § 1407(a).[2] "A pending motion before the JPML does not affect the jurisdiction of the transferor court." Falgoust v. Microsoft Corp., No. CIV.A. 00-0779, 2000 WL 462919, at *1 (E.D. La. Apr. 19, 2000).[3]

---

[2]28 U.S.C.A. § 1407(a) provides:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated: Provided, however, That the panel may separate any claim, cross-claim, counter-claim, or third-party claim and remand any of such claims before the remainder of the action is remanded.

28 U.S.C.A. § 1407(a).

[3]Indeed, Rule 1.5 of the Rules of Procedure of the JPML

A court, however, has "inherent power to 'control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.'" Id. (quoting Landis v. N. Am. Co., 299 U.S. 248, 254 (1936)). Consequently, the Court has discretion to grant a stay of proceedings in this case pending the JPML's decision on the pending motions to transfer. McCrary v.

---

states:

> The pendency of a motion, order to show cause, conditional transfer order or conditional remand order before the Panel concerning transfer or remand of an action pursuant to 28 U.S.C. § 1407 does not affect or suspend orders and pretrial proceedings in the district court in which the action is pending and does not in any way limit the pretrial jurisdiction of that court. A transfer or remand pursuant to 28 U.S.C. § 1407 shall be effective when the transfer or remand order is filed in the office of the clerk of the district court of the transferee district.

J.P.M.L. R. 1.5.

Bayer Corp., No. CIV.A. 02-642, 2002 WL 1467691, at *1 (E.D. La. July 3, 2002). Indeed, courts frequently grant stays pending transfer decisions by the JPML to avoid duplicative efforts and to promote judicial economy. Smith v. Mail Boxes, Etc. USA, Inc., 191 F. Supp. 2d 1155, 1157 (E.D. Cal. 2002) (collecting cases); Tench v. Jackson Nat'l Life Ins. Co., No. 99 C 5182, 1999 WL 1044923, at *1 (N.D. Ill. Nov. 12, 1999). "When considering a motion to stay, the district court should consider three factors: (1) potential prejudice to the non-moving party; (2) hardship and inequity to the moving party if the action is not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases are in fact consolidated." Rivers v. Walt Disney Co., 980 F. Supp. 1358, 1360 (C.D. Cal. 1997).

For the following reasons, the Court finds that staying this action pending the JPML's decision on the motions to transfer is appropriate. First, the JPML has scheduled a hearing on the motions to transfer for May 29, 2008, and, based on the Court's own experience with the JPML, the JPML likely will rule on the pending motions to transfer within the next two to three months. Plaintiffs and the remaining Defendants will suffer little, if any, prejudice from such a short stay.

Second, Defendant Baxter will suffer prejudice and hardship if the Court does not grant a stay in this action. If the Court does not grant a stay, Defendant Baxter will be required to develop and to present similar defenses in several district courts, and will have to engage in duplicate briefing of motions and potentially duplicative discovery.

Third, staying the proceedings in this case will promote judicial economy and efficiency. If the JPML ultimately transfers this case to another district court, the Court will have needlessly expended its energies and resources to familiarize itself with this case. Rivers, 980 F. Supp. at 1360. Further, any efforts that this Court might make with respect to case management and discovery "will most likely have to be replicated by the judge [who] is assigned to handle the consolidated litigation if the [JPML] does not consolidate the [Heparin] cases in this Court." Id. at 1361. Additionally, the transferee court may well be in a better position to address the other motions that remain pending in this case, such as the Joint Motion to Remand. Under those circumstances, granting a stay will conserve judicial resources.

For the above reasons, the Court finds that staying the proceedings in this case pending the JPML's decisions on the pending motions to transfer, is appropriate. The Court therefore grants Defendant Baxter's Motion to Stay.

III. Conclusion

ACCORDINGLY, the Court **GRANTS** Defendant Baxter Healthcare Corporation's Motion to Stay Proceedings Pending Transfer to the Judicial Panel on Multidistrict Litigation [11], and **STAYS** the proceedings in this case pending the JPML's decision on the pending motions to transfer. The Court **DEFERS** ruling on all of the other pending Motions in this case pending a decision by the JPML concerning the Motion to Transfer, including: (1) the Motion to Dismiss filed by Defendants Hamilton Health Care System, Inc. and Hamilton Medical Center, Inc. [3]; (2) the

Motion to Dismiss filed by Defendants Maxwell and N.W. Georgia Hematology and Oncology, P.C. [5]; (3) Plaintiffs' Motion Requesting the Court to Toll Time for the Filing by Plaintiffs of a Medical Malpractice Affidavit [8]; (4) the Joint Motion to Remand to State Court [12]; and (5) Plaintiffs' Motion to Dismiss John C. Church and Dalton Imaging Center [14].

IT IS SO ORDERED, this the 7th day of May, 2008.

UNITED STATES DISTRICT JUDGE